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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,618

05/25/2005

Andreas Bergmann

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7130

7590 12/15/2009  
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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

MAIL DATE

DELIVERY MODE

12/15/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,618	<b>Applicant(s)</b> BERGMANN, ANDREAS	
	<b>Examiner</b> NORA M. ROONEY	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4 and 15 is/are rejected.
- 7) ☒ Claim(s) 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

1. Applicant's response filed on 09/15/2009 is acknowledged.
2. Claims 1, 4, 15 and 17 are pending and under consideration as they read on a method for determining an increased risk of sepsis in a patient following a sepsis-risk event, said method comprising determining the amount of anti-asialo-GM1 antibodies (anti-AG<sub>MI</sub> antibodies) of the IgG and/or IgA type in blood, a blood fraction of a patient following a sepsis-risk event, wherein an elevated concentration of anti-asialo-GM1 antibodies in said blood compared to a healthy individual is indicative of an increased risk of sepsis.
3. The following rejections are necessitated by the amendment filed on 09/15/2009.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewartowska et al. (PTO-892; Reference U) as evidenced by Rangel Frausto et al. (PTO-892; Reference X).

Lewartowska et al teaches a method for determining the amount of anti-asialo-  $G_{M1}$  antibodies of the IgG type in serum (blood fraction) of a patient following acquiring thyroid cancer (sepsis-risk event) with an ELISA sandwich assay and comparing the level to a healthy individual (In particular, 'Materials and Methods' and whole document).

The recitation of "determining an increased risk of sepsis in a patient following a sepsis-risk event" in claim 1 is inherent. The same active method steps are being performed in the same patient population, so the result is inherent.

Claims 1 and 4 are included in this rejection because, absent a limiting definition in the specification, acquiring thyroid cancer is a sepsis risk event. In addition, Rangel Frausto et al. is being used as an evidentiary reference to show that cancer is a sepsis risk event (In particular, page 675, first full paragraph).

The reference teachings anticipate the claimed invention.

6. Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Witkin et al. (PTO-892; Reference V) as evidenced by Rangel Frausto et al. (PTO-892; Reference X).

Witkin et al teaches a method for determining the amount of anti-asialo-  $G_{M1}$  antibodies of the IgG type in serum (blood fraction) of a patient following acquiring AIDS (sepsis-risk

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event) with an ELISA sandwich assay and comparing the level to a healthy individual (In particular, 'Materials and Methods' and whole document).

The recitation of "determining an increased risk of sepsis in a patient following a sepsis-risk event" in claim 1 is inherent. The same active method steps are being performed in the same patient population, so the result is inherent.

Claims 1 and 4 are included in this rejection because, absent a limiting definition in the specification, acquiring AIDS is a sepsis risk event. In addition, Rangel Frausto et al. is being used as an evidentiary reference to show that AIDS is a sepsis risk event (In particular, page 675, first full paragraph).

The reference teachings anticipate the claimed invention.

7. Claims 1, 4 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Adair et al. (PTO-892; Reference W).

Adair et al teaches a method for determining the amount of anti-asialo-  $G_{M1}$  antibodies of the IgG type in serum (blood fraction) of a patient following heart transplantation (sepsis-risk event, surgery) with an ELISA sandwich assay and comparing the level to a healthy individual (In particular, 'Materials and Methods,' abstract, whole document).

The recitation of "determining an increased risk of sepsis in a patient following a sepsis-risk event" in claim 1 is inherent. The same active method steps are being performed in the same patient population, so the result is inherent.

The reference teachings anticipate the claimed invention.

8. Claim 17 is objected to as being dependent upon rejected base claim 1, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937.

The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A

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message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 4, 2009

Nora M. Rooney

Patent Examiner

Technology Center 1600

/Maher M. Haddad/

Primary Examiner,

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